

AZEE-500 TABLETS

Azithromycin 500mg

What is in this leaflet

1. What AZEE is used for
2. How AZEE works
3. Before you use AZEE
4. How to use AZEE
5. While you are using it
6. Side effects
7. Storage and Disposal of AZEE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What AZEE is used for

Azithromycin belongs to macrolide antibiotics, known as azalides. It is used to treat bacterial infections.

AZEE is used in the treatment of the following infections:

- Lower respiratory tract: bronchitis (inflammation of bronchi) and pneumonia (inflammation of lung's air sacs).
- Upper respiratory tract: sinusitis (inflammation of sinus lining) and pharyngitis/tonsillitis (inflammation of throat/tonsils).
- Acute otitis media (ear infection).
- Skin and soft tissues.
- Sexually-transmitted diseases: Uncomplicated genital infections caused by *Chlamydia Trachomatis* or *Neisseria gonorrhoea*, chancroid caused by *Haemophilus ducreyi*.

How AZEE works

AZEE works by suppressing the protein synthesis in bacteria, by binding to ribosomal subunit 50s which causes inhibition in peptide translocation.

Before you use AZEE

-When you must not use it

Do not take AZEE if you are allergic to azithromycin, other macrolide or ketolide antibiotics, or any of the excipients of AZEE.

Pregnancy and lactation

Do not use AZEE if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not use AZEE if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor if you suffer from any of the following illnesses:

- If you have a serious kidney condition.
- If you have a severe liver condition.
- If you are currently taking ergotamine derivatives and azithromycin.
- If you have heart disease or have electrolyte abnormalities or prolonged QT interval.
- If you have diarrhoea during or after medication.
- If you have allergic reaction.
- As with all antibiotics.

Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Azithromycin may interact with other medicines. It is important that you mention if you taking, or have taken any of the following medication:

- Medications for treating migraines such as *Ergot*
- Medicines used to prevent blood clots such as Coumarin-type oral anticoagulants
- Medications used in heart failure such as *Digoxin*
- Medicines used in lowering cholesterol such as *Atorvastatin*
- Medicines used for sedation such as *Midazolam*
- Medicines used in the treatment of fungal/bacterial infections such as *Fluconazole*, *Rifabutin*, *Trimethoprim/sulfamethoxazole*
- Medicines used in the treatment of asthma such as *Theophylline*
- Medicines used in transplant

patients such as *Cyclosporin*

- Medicines used to treat allergies such as *Terfenadine*, *Cetirizine* and *Methylprednisolone*
- Medicines used in the treatment of HIV/AIDS such as *Didanosine*, *Indinavir*, *Efavirenz*, *Zidovudine* and *Nelfinavir*
- Medicines used in treating high blood pressure in lungs such as *Sildenafil*
- Medicines used as anticonvulsant such as *Carbamazepine*
- Medications used for digestive problems such as *Antacids* and *Cimetidine*
- Medicines used for treating sleep problems such as *Triazolam*

How to use AZEE

-How much to use

- Always take AZEE exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
- The usual dose is one tablet (250mg or 500mg) taken once a day. The maximum recommended total dose for any treatment is 1500mg. Your pharmacist will explain how to use it if you are not sure.
- *Azithromycin* tablets should only be administered to children weighing more than 45kg.

-When to use it

AZEE should be administered as a single daily dose. The tablets can be taken with or without food.

-How long to use it

Your doctor will tell you how long you should take AZEE.

-If you forget to use it

Do not take a double dose to make up for a forgotten dose. Take AZEE as soon as you remember.

-If you use too much (overdose)

Contact your doctor immediately

AZEE-500 TABLETS

Azithromycin 500mg

or go the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause severe nausea, vomiting and diarrhoea and reversible hearing loss.

While you are using it

-Things you must not do

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor of you think you are (or might become) pregnant, or if you are breastfeeding.

-Things you must not do

Do not stop the treatment early as there may be a risk of relapse of the illness.

-Things to be careful of

No studies have been conducted to evaluate the effect of azithromycin on the ability to drive or use machines. However, the possibility of undesirable effects such as dizziness and convulsions should be considered.

Side effects

Like all medicines, AZEE can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common effects include diarrhea, abdominal pain, nausea, and flatulence (wind).

Common side effects include indigestion, drowsiness, dizziness, headache, tingling or prickling sensation, change in taste, change in visual, loss of hearing, vomiting, loss of appetite, rash, itchiness, joint pain, tiredness, and decrease or increase in certain blood cell count.

If you experience any of the side

effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- AZEE may cause severe allergy and serious skin reactions. Stop using AZEE and seek medical assistance immediately if you experience any of the following symptoms: skin reddening, blisters, rash, fever, sore throat or eye irritation.

- If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines(AEFI))).

Storage and Disposal of AZEE

-Storage

Store at temperature below 30°C. Keep all medicines out of reach of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

White to off-white film coated capsule shaped biconvex tablets plain on one side and central breakline on the other.

-Ingredients

Active ingredients:

Azithromycin

Inactive ingredients:

Dibasic Calcium Phosphate (Dihydrate), Croscarmellose Sodium (Ac-di-Sol), Maize Starch, Povidone (PVP K-90), Magnesium Stearate, Sodium Lauryl Stearate, Opadry White 04F58804 (HPMC 2910/Hypromellose 15 Cp, Titanium Dioxide, Macrogol/PEG 6000).

-MAL number

MAL11030117AZ

Manufacturer

CIPLA LTD.
Plot No. S-103 to S-105, S-107 to S-112, L-138, L-147. L-147/1 to L-147/3 & L-147/A
Verna Industrial Estate, Verna
Salcette, Goa India.

Product Registration Holder

Cipla Malaysia Sdn Bhd
Suite 1101, Amcorp Tower,
Amcorp Trade Centre,
18 Persiaran Barat, 46050
Petaling Jaya, Selangor,
Malaysia.

Date of Revision

29/11/2022

Serial number

NPRA (R2/1)220430/667